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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,896	10/19/2000	Mark H. Theno	1335.001US1	7633

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EXAMINER

CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/691,896

Applicant(s)

THENO, MARK H.

Examiner

Yong S. Chong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-14,17-31,38-40 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10-14, 17-31, 40, 42-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 10, 2005 has been entered.

Claims 2, 9, 15-16, 32-37, 41 have been cancelled. Claims 38-39 have been withdrawn. Claims 1, 5, 10, 25 have been amended. Claims 42-44 have been added. Claims 1, 3-8, 10-14, 17-31, 40, 42-44 are pending and are examined herein.

Response to Arguments

Applicant's arguments filed on October 18, 2004 have been fully considered and found not persuasive.

Applicant assert that the Cartmell et al. reference does not teach a vapor emitting material that is a drug, a pheromone, or a perfume. Applicant further asserts that the Fischel-Ghodsian et al. and Wick et al. references describe a device for releasing vapors absent a hydrogel. Finally, applicant states that there is no motivation for combining these references.

In response to applicant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on

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the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Firstly, the motivation to substitute the polyolefin foam of Cartmell et al. with the polyolefin foam taught by Fischel-Ghodsian et al. is because of the increased porosity of the cell sizes in the foam. Hence, the modification of the invention described by Cartmell et al. by substituting the existing polyolefin foam with superior polyolefin foam described by Fischel-Ghodsian et al. is indeed the motivation. Thus, the inclusion of vapor emitting material in the foam taught by Fischel-Ghodsian et al. is warranted. What's more, the vapor emitting material contains active ingredients that are classified as drugs, pheromones, and perfumes. An excellent example of a vapor emitting material with low vapor pressure is a perfume, since it is a volatile liquid distilled from flowers or prepared synthetically.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-8, 10-12, 17-20, 23-27, 29-30, 40, 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. (US Patent 5,501,661) in view of Fischel-Ghodsan et al. (US Patent 5,455,043).

Cartmell et al. teach a wound dressing product containing a porous layer. The wound dressing product comprises an optional release liner, an optional removable tab, and a wound dressing. The wound dressing comprises a thin-film layer, an adhesive layer, a porous backing layer, an optional support layer and a hydrogel material. The thin-film layer has a first side and an opposing second side and forms the outer surface of the dressing product. The adhesive layer is positioned on the second side of the thin-film layer. The backing layer is constructed of a porous material comprising a polyolefin foam (col. 2, lines 19-32). The porous backing layer has a first side and an opposing second side, and is adhered to the second side of the thin-film layer by the adhesive layer. The optional support layer is made from a material such as woven and non-woven fabrics. The hydrogel material may be secured to the second side of the support layer. The permeable fabric of the support layer allows the hydrogel material to pass through to the first side of the support layer. The optional release liner overlies the hydrogel material and is secured to the perimeter portion of the second side of thin-film layer by means of the adhesive layer. The optional removable tab is interposed between the thin-film layer and the release liner. The porous layer obviates the need for a second adhesive layer, and is moisture and vapor permeable (col. 2, lines 36-58). Cartmell et al. clearly teach that the invention is designed to permeate vapor "which

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permits the transpiration of moisture through the wound dressing." Thus, the reference clearly teaches that a skilled artisan would have expected that the invention be used to transport vapors.

While the reference does not explicitly state that vapor emitting materials are stored within the foams, examiner respectfully points out that it is implicit in the teachings of Cartmell et al., as the foam layer is the layer through which oxygen and other vapor-permeable substances are transferred from the wound to the environment. The reference teaches that the structure of the patch as claimed is well known in the art, except that the reference is silent as to the cellular structure of the foam. The reference fails to teach that a vapor emitting material is stored in the patch "prior to use."

Fischel-Ghodsian et al. teach patches comprised of foams, such as polyolefin, polypropylene, and polyethylene foams. The reference teaches that varying the porosity of the cellular structure of the foam is within the skill of the art (col. 5, lines 14-25). The reference teaches that the active ingredients in the vapor emitting compounds can be perfumes, various fragrances, air fresheners, insecticides, and insect repellents. The active agent can also be therapeutic agents such as vapor emitting compounds, and those which are typically delivered by aerosol or spray inhalation. These therapeutic agents include antihistamines, bronchodilators, decongestants, anti-tussives, mucolytics, steroids, anti-virals, hormones, and peptides (col. 4, lines 1-9). These active ingredients are incorporated in the reservoir layer of the patch (col. 6, line 56 to col. 7, line 7).

It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to modify the polyolefin foams of Cartmell et al. with suitable polymers that possess a diffusion rate limiting membrane layer as taught by Fischel-Ghodsian et al. because using such polymers (polyolefin foams) will enable one to control the amount and rate of emission of the active agent due to the porosity of the cell sizes of the membrane. Incorporation of vapor emitting compounds in the foams of Cartmell et al. is viewed as an obvious variation of the prior art in view of Fischel-Ghodsian et al. because the skilled artisan would have been motivated to successfully produce a therapeutic medication.

Claims 13, 14, 21, 22, 28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. in view of Fischel-Ghodsian et al. as applied to claims 1, 3-8, 10-12, 17-20, 23-27, 29-30, 40, 42-44 as above, and further in view of Wick et al. (US Patent 6,010,715).

Cartmell et al. and Fischel-Ghodsian et al. are applied as discussed above. The references lack a teaching of the release layer made from polyolefin, polyamide, cellulosic, or polyethylene terephthalate.

Wick et al. teach transdermal patches. The backing layer is taught as being made from cellulose acetate, ethyl cellulose, polyethylene terephthalate and other materials. These compounds are taught as being made of a material that is substantially impermeable to the layer or layers with which it can be in contact. The patches are taught as being kept sealed in an air-tight pouch prior to use (col. 14, lines 34-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the release liner material of Cartmell et al. with

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cellulose acetate, ethyl cellulose, or polyethylene terephthalate, as taught by Wick et al. because of the expectation of achieving a product that is impermeable to the hydrogel, thereby keeping the product intact.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the patches of the combined references as being kept sealed in an air-tight pouch prior to use, and thereby having to remove the patch from the seal for use, as taught by Wick et al., because of the expectation of achieving a patch that is sterile.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should


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Business Center (EBC) at 866-217-9197 (toll-free).

YSC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER